

REMARKS

This response is submitted within two months of the June 15, 2006 mailing of the final Office Action in this case. Claims 1-35 remain pending in the application. In the Office Action, the Examiner:

- allowed claims 1-15 and 25-35;
- rejected pending claims 16, 23 and 24 under 35 U.S.C. § 103(a) as obvious in view of U.S. Patent No. 5,741,256 to Bresina (hereinafter “Bresina”) in combination with U.S. Patent No. 6,059,785 to Schavan et al. (hereinafter “Schavan”); and
- objected to pending claims 17-22 as being dependent upon a rejected base claim, but otherwise allowable if rewritten in independent form.

As discussed more fully below, Applicants respectfully traverse the obviousness rejection of claims 16, 23 and 24 because the cited Bresina and Schavan references are not properly combinable.

**Claim Rejections - 35 U.S.C. § 103(a)**

Claims 16, 23 and 24 were rejected as obvious under 35 U.S.C. § 103(a) in view of Bresina in combination with Schavan. Bresina discloses an implant, e.g., an osteosynthetic nail, having a plurality of blades fixed to a proximal portion of a shaft. The Bresina implant is hammered into position, and may be used with a side plate or an intramedullary nail to repair femoral fractures. (Bresina at Abstract.) The Bresina invention is intended to minimize the tendency of the implant to fail by cutting through cancellous bone tissue after implantation. (Bresina at col. 2, ll. 10-14.) Schavan discloses a bone screw having a tip shaped like a drill to provide a self-drilling feature, with at least part of the shaft of the screw being threaded. (Schavan at col. 2, ll. 5-16.) The Schavan screw may be used to attach bone plates and other fixation components, and is screwed into position using a screwdriver. (*Id.* at col. 2, ll. 58-67.)

In the Office Action, the Examiner notes that Bresina fails to disclose the claimed “bladed portion that has a smaller maximum outer diameter than maximum outer diameter of the non-bladed portion.” However, the Office Action states that:

[I]t would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Bresina having at least a bladed portion with a *smaller maximum outer diameter* than the non bladed portion in view of Schavan et al. to better fit the implant in the femoral socket.

(6/15/06 Office Action at 3 (citations omitted).)

Applicants respectfully traverse the rejections of claims 16, 23 and 24 based on the combination of Bresina with Schavan because the Office Action fails to make a *prima facie* case of obviousness. More particularly, there can be no *prima facie* case of obviousness if a proposed modification of the prior art “would render the prior art invention being modified unsatisfactory for its *intended purpose*.<sup>1</sup> MPEP § 2143.01.V. Similarly, “if the proposed modification or combination of the prior art would change the *principle of operation* of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious.” MPEP § 2143.01.VI.

As noted in the Office Action, Bresina does *not* disclose an implant where “the maximum outer diameter of the bladed portion is smaller than the maximum outer diameter of the non-bladed portion,” as recited in independent claim 16. As shown in FIGS. 1, 3 and 4 of Bresina and discussed in the specification, Bresina teaches an implant with blades 12 that are *wider* than the shaft portion 16 of the implant — “[t]he tapered blades 12 are *widest at their distal ends* 18 and taper down, in the direction of their proximal ends 20, until they lie flush with the outer surface of the proximal portion 14 of the shaft 16.” (Bresina at col. 3, ll. 22-26.) Bresina also makes clear that the greater width of the blades contributes directly to one of the key objects of the Bresina invention — minimizing the tendency of the implant to cut through the cancellous bone tissue after implantation:

[T]he *wide proximal portions* of the uniform blades 10 provides a *large surface* normal to the principal downward load imposed on the femoral head 36 when the patient stands and ambulates. This reduces the pressure on the cancellous tissue within the femur 29 and *resists the tendency to cut through* the bone cortex.

(Bresina at col. 4, ll. 10-16.) The greater width of the blades also beneficially contributes to additional *flexibility* of the proximal portion of the implant, so that it “may flex, rather than carve through, or crush, bone tissue.” (*Id.* at col. 4, ll. 20-25.) Therefore, the greater blade width of Bresina is critical to the *intended purpose* and *principle of operation* of the Bresina

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<sup>1</sup> All emphasis added.

invention.

Despite the critical importance of the *larger* Bresina blade width to the operation and purpose of the Bresina invention, the Office Action states that it would have been obvious “to construct the device of Bresina having at least a bladed portion with a *smaller* maximum outer diameter than the non bladed portion in view of Schavan et al. to better fit the implant in the femoral socket.” (June 15, 2006 Office Action at 3.) But this rejection is clearly improper because the cited combination would both render the prior art Bresina implant unsatisfactory for its *intended purpose* and change its basic *principle of operation*. MPEP § 2143.01.V, VI. For example, reducing the maximum diameter of the blades of the Bresina implant, as the Office Action suggests, would *reduce* the surface area of the implant normal to the principal downward load, thereby *increasing* the pressure on the cancellous tissue within the femur and *increasing* the tendency to cut through the bone cortex. This is completely opposite to the express teachings and *intended purpose* of Bresina, which discloses greater blade width for *increased* surface area and *reduced* pressure on the surrounding bone. (Bresina at col. 4, ll. 10-16.) Similarly, this proposed modification would also clearly change the basic *principle of operation* of the Bresina implant.

Accordingly, applicants respectfully request that the obviousness rejection of claim 16, based upon the combination of Bresina with Schavan, be withdrawn and that this claim, and each of its dependent claims 17-24, be allowed.

**Allowable Subject Matter**

Applicants would like to thank the Examiner for the allowance of claims 1-15 and 25-35, and the indication of allowable subject matter in claims 17-22.

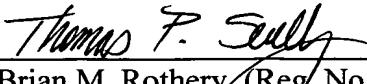
In view of the remarks above, Applicants respectfully request that the Examiner reconsider pending claims 16-24 with a view towards allowance. The Examiner is invited to call the undersigned attorney at (212) 326-3939 if a telephone call could help resolve any remaining issues.

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No additional fees are believed due with this submission. However, should any additional fees be required, please charge such fees to Jones Day deposit account no. 50-3013.

Respectfully submitted,

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